



### Konformitätserklärung / Declaration of Conformity

Virotech Diagnostics GmbH, Waldstrasse 23 A2, 63128 Dietzenbach, Deutschland, erklärt in alleiniger Verantwortung, gemäß der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostika, dass folgende Produkte die grundlegenden Anforderungen gemäß Anhang I der Richtlinie 98/79/EG erfüllen und dass das Konformitätsbewertungsverfahren nach Anhang IV ohne Abschnitt 4 und 6, Richtlinie 98/79/EG, für Produkte Anhang II Liste B durchgeführt wurde.

Benannte Stelle: mdc medical device certification GmbH, Kriegerstraße 6, 70191 Stuttgart, Kennnummer: 0483.

*Virotech Diagnostics GmbH, Waldstrasse 23 A2, 63128 Dietzenbach, Germany, declares under sole responsibility and referring to the Directive 98/79/EC of the European Parliament and the Council on In-Vitro-Diagnostics dated 27<sup>th</sup> October 1998 that the following products fulfil the basic requirements according to Annex I, Directive 98/79/EC and that the conformity assessment module acc. to Annex IV without section 4 and 6, Directive 98/79/EC for products classified as Annex II, List B has been applied.*

*Notified body: mdc medical device certification GmbH, Kriegerstraße 6, 70191 Stuttgart,*

| Produktname<br>Product Name | Art. Nummer<br>Order # |
|-----------------------------|------------------------|
|-----------------------------|------------------------|

#### CMV (Cytomegalovirus)

|                                  |          |
|----------------------------------|----------|
| VIROTECH CMV IgG/IgM ELISA       | EC113.00 |
| CMV IgG/IgM MTP                  | EC113.01 |
| CMV IgG Ctrl-Set                 | EN113K60 |
| CMV IgG Liquor/CSF Standards     | EC113L60 |
| CMV IgG ELISA neg. Ctrl          | 111301   |
| CMV IgG ELISA Cut off Ctrl       | 111302   |
| CMV IgG ELISA pos. Ctrl          | 111303   |
| CMV IgG Liquor/CSF STD1 (1,5wME) | 111330   |
| CMV IgG Liquor/CSF STD2 (6,2wME) | 111331   |
| CMV IgG Liquor/CSF STD3 (25wME)  | 111332   |
| CMV IgG Liquor/CSF STD4 (100wME) | 111333   |
| CMV IgM Ctrl-Set                 | EN113K80 |
| CMV IgM ELISA neg. Ctrl          | 111304   |
| CMV IgM ELISA Cut off Ctrl       | 111305   |
| CMV IgM ELISA pos. Ctrl          | 111306   |

Dietzenbach, 2022-03-07

Rodrigo Berrie

Geschäftsführer / Managing Director

VIROTECH Diagnostics GmbH

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Die nächste Überprüfung der Konformitätserklärung erfolgt spätestens zum 2023-03-07.  
*The next verification of the declaration of conformity is scheduled for 2023-03-07.*

## Supplement to declaration of conformity

We, Virotech Diagnostics GmbH, declare in addition to the declaration of conformity,  
Rev 47:

The validity date indicated on the declaration of conformity refers to the end of the transitional period, according to Article 110 of Regulation EU 2017/746, for the placing on the market of products with a certificate (according to IVD directive 98/79/EC) by a Notified Body.

By Regulation (EU) 2022/112 of the European Parliament and of the Council of 25.01.2022, the validity of our directive certificate could be extended to 2025-05-26.

The individual controls of the VIROTECH CMV IgG/IgM ELISA are only available in the Ctrl-Set.

Single controls and microtiter plates can no longer be ordered.

Dietzenbach, 2023-03-15



**Brigitte Ott-Schnetter**  
(Quality Management)